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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,851	03/23/2005	Philip C. Roy	2870(203-3505)	6326
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Tyco Healthcare Group LP 60 MIDDLETOWN AVENUE NORTH HAVEN, CT 06473				
EXAMINER				
TRUONG, THANH K				
ART UNIT		PAPER NUMBER		
3721				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/528,851

Applicant(s)

ROY, PHILIP C.

Examiner

THANH K. TRUONG

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2 and 5-18 is/are pending in the application.
- 4a) Of the above claim(s) 10-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2 and 5-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
- Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. This action is in response to Applicant's amendment received on December 6, 2007.

2. Applicant's cancellation of claims 3, 4 and 19 is acknowledged.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1, 8, 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Viola et al. (5,954,259) in view of Mizzy et al. (3,859,996).

Viola et al. discloses an apparatus comprising:

a housing having a fixed handle (20) - It is construed that the housing in Viola et al. comprises the frame portions that cover all components of the apparatus (10) – see figure 1;

a clamping handle (44) mounted to the housing and selectively movable relative to the fixed handle from a first position in spaced relation relative to the fixed handle to a second position closer to the fixed handle to actuate the clamping of tissue;

an adapter yoke (76) which translates within the housing upon actuation of the clamping handle, the adapter yoke mechanically cooperating with a lead

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screw (78) disposed within the housing to actuate the tool assembly to clamp tissue;

a drive assembly (22) disposed within the housing, the drive assembly including a shaft (42), the shaft being mechanically engaged with the lead screw (78) disposed within the housing such that upon selective activation of the drive assembly, the shaft rotates said lead screw to advance a roll nut (94) distally along the lead screw to force a firing piston into a tool assembly when mounted on the housing to deform the surgical fasteners through and fastening the tissue (figures 9 & 10).

Viola et al. discloses the claimed invention, but it does not expressly disclose that the drive assembly is selectively variable to regulate the speed at which the surgical fasteners are deformed, and the stapler comprises a pressure sensitive trigger.

Mizzy et al. discloses an apparatus that comprises a pressure sensitive trigger mechanism (abstract) that provides a means to effectively controlling the drive assembly.

Mizzy et al. demonstrates that it is old and well known in the art to use the pressure sensitive trigger to activate and regulate the drive assembly of an apparatus so that drive assembly is selectively variable to regulate the speed at which the surgical fasteners are deformed, and the stapler comprises a pressure sensitive trigger to provide a more accurately control of the stapler device.

Therefore, it would have been obvious to one having ordinary skill in the art, at the time applicant's invention was made, to have modified Viola et al.

apparatus by incorporating the pressure sensitive trigger mechanism as taught by Mizzy et al. so that it comprises the drive assembly that is selectively variable to regulate the speed at which the surgical fasteners are deformed, and the stapler comprises a pressure sensitive trigger mechanism to provide a more responsive and more precise surgical instrument.

Regarding claims 8 and 9, the modified Viola et al. by Mizzy et al. further discloses: wherein the stapler includes a switch for reversing the rotation of the shaft of the drive assembly upon activation thereof (Viola et al. - column 5, lines 7-12), and the shaft (42) rotates upon activation of the drive assembly (22), which in turn rotates the lead screw (78).

5. Claims 2, and 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Viola et al. (5,954,259) in view of Mizzy et al. (3,859,996) and further in view of Green et al. (US 2002/0096550).

As discussed above in paragraph 4 of this office action, the modified Viola et al. discloses the claimed invention, but does not expressly disclose that: the drive assembly is pneumatic powered, the safety mechanism as describe in claims 5 and 7.

It is old and well known in the art to employ a pneumatic drive assembly in place of electrical or hydraulic drive assembly and it is also well known to have a safety mechanism in a surgical stapler to prevent accidental triggering of the device.

Green et al. discloses a surgical stapler that comprising: a pneumatic drive assembly (68) to provide a simple and compact drive system, and a safety mechanism to prevent from accidentally firing of the tool (page 6, [0102]).

Therefore, it would have been obvious to one having ordinary skill in the art, at the time applicant's invention was made, to have modified Viola et al. apparatus by incorporating the pneumatic drive assembly for a more compact and simple drive system and the safety mechanism as taught by Green et al..

Response to Arguments

6. Applicant's arguments filed December 6, 2007 have been fully considered but they are not persuasive.

7. In response to the Applicant's argument that:

"Combining Mizzy with Viola does not provide a surgical stapler having a "clamping handle" for actuating the clamping of tissue and "pressure sensitive trigger" for regulating the deformation of the surgical fasteners, as recited in claim 1. Therefore, Applicant respectfully submits that claim 1, is not anticipated or fairly suggested by Viola in view of Mizzy, and is in condition for allowance. Since claims 8 and 9 depend from claim 1, it is respectfully submitted that, for at least the this reason, claims 8 and 9 are also in condition for allowance",

this is not found persuasive for the following reasons:

Mizzy et al. is relied upon for the teaching of a "pressure sensitive trigger", a trigger that actuates and regulates the pressure of a pneumatic instrument. It is maintained that Mizzy et al. "pressure sensitive trigger" responses to the triggering action and in turn regulates the pressure of an pneumatic instrument.

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Applicant's disclosure stated that: "trigger 580 cooperates with trigger valve 590 to regulate the pneumatic pressure to the pneumatic drive assembly 520" (page 17, lines 21 to page 18, lines 1) and "pressure sensitive trigger 580 is utilized to activate the pneumatic drive assembly 520" (page 18, lines 7-8).

Accordingly, it is believed that Mizzy et al. discloses the "pressure sensitive trigger" as recited in claim 1.

Furthermore, it should be pointed out that it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

8. In response to the Applicant's argument that:

"Claims 2 and 5-7 were rejected under 35 USC § 103(a) as being anticipated by Viola in view of Mizzy and in further view of U.S. Patent Application No. 2002/0096550 to Green et al (hereinafter "Green"). As noted above, Viola in view of Mizzy does not disclose or suggest all of the features of claim 1, the base claim from which claims 2 and 5-7 depend. Green does not provide any further disclosure or suggestion that, in combination with Viola in view of Mizzy, would suggest the surgical stapler of claim 1. Since, neither Viola in view of Mizzy, nor Viola in view of Mizzy in further view of Green, suggest the elements of claim 1, and claims 2 and 5-7 depend from claim 1, for at least the reasons presented above, it is respectfully submitted that the rejection of the Office Action has been overcome and that claims 2 and 5-7 are in condition for allowance",

this is not found persuasive for the following reason:

Green et al. is relied upon to demonstrate that it is old and well known in the art to employ a pneumatic drive assembly in place of electrical or hydraulic

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drive assembly and it is also well known to have a safety mechanism in a surgical stapler to prevent accidental triggering of the device.

Therefore, it is maintained that it is proper to combine Viola et al., Mizzy et al. and Green et al. as discussed above in paragraph 5.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to THANH K. TRUONG whose telephone number is (571)272-4472. The examiner can normally be reached on Mon-Fri 9:00AM - 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rinaldi Rada can be reached on 571-272-4467. The fax

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phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

tkk
March 28, 2008.

/Thanh K Truong/
Primary Examiner, Art Unit 3721.